EXHIBIT Q

OF550-010
CP1998SEF001
Appendix I

CONCEPT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

DESIGN SAFETY ASSESSMENT	REVISION: 1
	REVISION DATE: 6/6/02
Product Name:	GYNEMESH * PROLENE Soft Mesh
Product Code:	GPSL
RMC:	N/A
Project Leader:	Maggie D'Aversa 8/14/02
ANALYSIS TEAM	**ASSOCIATE NAME**
Development Engineer/Scientist:	Elbert Katrin
Manufacturing/Technical Services Engineer:	Irene Lee Maritza Molina
Quality Assurance Engineer:	Enilma Miller
Regulatory Affairs:	Sean O'Bryan
Other:	Richard Isenberg Paul Parisi 7-31-02 Cyrus Guidry 7.31.02

DISPOSITION/APPROVAL:	
Maggie D'Aversa Katrin Elbert **Development Engineer/Scientist**	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ____:Yes; ____:No.
Irene Lee/ Maritza Molina **Manufacturing Engineer**	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ____:Yes; ____:No.
Enilma Miller E. Miller **Quality Assurance Engineer**	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ✓:Yes; ____:No.
Sean O'Bryan **Regulatory Affairs**	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ✓:Yes; ____:No.

Medical Director: _____

ETHICON, INC.
OCT 0 1 2002
R&D - CENTRAL FILE

0206226

DEVICE SAFETY ASSESSMENT (DDSA) SUMMARY REPORT
(Revision 1

DEVICE: (*Provide a description of the overall device system*) **A non-absorbable polypropylene mesh, manufactured out PROLENE* monofilament fiber. The product is used for tissue reinforcement and long –lasting of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.**

SCOPE of the DESIGN SAFETY ASSESSMENT: (*Define the scope of this risk assessment*)

This risk assessment was completed on (*check one*): __X__ Device ____Subsystem ____Component

This DDSA is applicable to the GYNEMESH* PROLENE Soft mesh product and will identify any hazards associated with this new product offering.

Define the intended use of the reviewed item:

GYNEMESH™ PROLENE Soft Mesh is used for tissue reinforcement and long –lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Briefly, describe the revision to the device or sub-system that preceded a revision to the DDSA:

Initial version of DDSA.

Revision 1 Final DDSA document

ACTIVITY	YES/NO/NA	FILE REFERENCE	COMMENT
All qualitative and quantitative characteristics that could affect safety have been listed including their defined limits.	YES	D&D Plan & Material	
The intended use of the device is clearly defined, including: Indications/Contraindications and intended use The intended user, his required skill and training Interaction of device with the patient as user: The operational, transport, cleaning and storage environments have been considered:	YES	Re: GYNEMESH Product Insert	
Long term use of equivalent product has been considered from both the positive and negative perspective. Clinical/Scientific reports, both internal and published: Device failure reports:	YES	Re: Clinical and Scientific reports	Raw Materials and Indications for device similar to the Soft PROLENE mesh
The contact conditions and timing with the patient have been considered.	YES.	Re: Clinical and Scientific reports	Raw Materials and Indications for device similar to the Soft PROLENE mesh
Materials and components used for fabrication and manufacture have been considered. Chemical nature, quantitative formulation, additives, processing aids, monomers, catalysts, residues: Concentration, availability, toxicity: Biodegradation aging and corrosion: Previous use of this material, and long term effectiveness in equivalent application can be demonstrated: Appropriate biocompatability testing to EN 30993:	YES	Ref: Soft PROLENE Mesh Biocompatibility Strategy	Raw materials are chemically unchanged – The Soft PROLENE Resins utilized in clear and blue pigmented sutures have been utilized in the fabrication of this mesh.
The sterility of the device and its potential reuse, number of resterilizations possible and sterilization method, device storage, shelf-life, and disposal have been considered.	YES	Product Insert – Warnings section & 1) Sterilization 2) Storage Stability Strategy	Raw materials are chemically unchanged – Soft PROLENE Resin Do not re-sterilizer this product

ACTIVITY	YES/NO/NA	FILE REFERENCE	COMMENT
The accuracy and precision of measurement parameters executed by the device and their interpretation has been considered.	N/A	N/A	
The need for routine maintenance or calibration of the device, and the method of provision has been considered.	N/A.	N/A	
Interactions with other devices or drugs, and any potential problems have been considered.	YES	N/A	Raw material is chemically unchanged.
Delayed or long term use of the device, ergonomic and accumulative effects have been considered	YES	N/A	
A Device Specification exists.	YES	N/A	
A PBOM has been defined.	YES	N/A	
A requirement or finished goods specification is available.	YES	N/A	
Manufacturing and Material specifications are available.	YES	N/A	
Surgical technique, labels, warnings and other instructions for use (cleaning, sterilization, use, maintenance, and disposal) are available.	YES	Product Insert	See package Insert
Device marketing brochures, or other sales literature, have been considered.	YES	Indications&Claims Defined	Sales Literature

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
1 Intended Use	1) Is special training of the intended user needed?	X		If yes, please attach training plan
	2) Does use of the device impose any ergonomic factors or effects?	X		If yes, please attach plan.
	3) Are there any environmental factors that could influence safety/function of the device?	X		If yes, please define the limits.
	4) Can the patient control or influence the use of the device?	X		If yes, please define the training plan for the user.
	5) Is device safety/functionality compromised based upon the patient (such as elderly, diabetic, handicapped, or other)?	X		If yes, please define the nature of the compromise and the limits.
2 Patient Contact	6) Does device use utilize surface contact to the patient?		X	Permanent prosthetic implant.
	7) Does device use utilize invasive contact with the patient?		X	Permanent prosthetic implant.
	8) Does device use require implantation?		X	Permanent prosthetic implant.
3 Materials	9) Define the materials utilized in the construction of the device. **Highlight** those materials that will involve direct patient contact		X	Prolene - Polypropylene (blue pigmented and clear). The processes utilized in the manufacture of the material are unchanged relative to Soft PROLENE mesh.
	10) Have the materials been tested for toxicity and biocompatability?		X	Ref: DHF of Soft PROLENE - Biocompatibility section from T. Barbolt.
	11) Have the materials been tested for carcinogenicity, teratology, and mutagenicity (as appropriate)?		X	Ref: DHF Soft PROLENE Mesh
	12) Is the strength of load-bearing materials sufficient for the intended use?		X	Ref.: Clinical Literature search

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
4 Energy	13) Is energy delivered to and/or extracted from the patient?	X		If no, proceed to the next section.
	14) Describe the type of energy transferred.			
	15) Is the energy output is controlled, in terms of quality, quantity, and time-function			
5 Substances	16) Are substances delivered to and/or extracted from the patient?	X		
	17) Is the device absorbable?	X		If yes, please attach a listing of all by-products produced during the devices in-situ degradation
	18) If the device is absorbable, have all of the materials identified above been tested for biocompatability at the appropriate concentrations?	X		If yes, please identify the location of appropriate reports.
	19) Is the transfer rate (delivery/extraction) of substances controlled?	X		If yes, please describe how the transfer rate is controlled.
	20) What is the maximum/minimum substance transfer rate?			
6 Biological Materials	21) Are biological materials processed by the device for subsequent re-use?	X		If not, proceed to the next section.
	22) Is the device disposable?			
	23) Are those components contacting biological materials cleanable and sterilizable?			
	24) Are those components contacting biological materials compatible?			
7 Sterility - Supplied Sterile	25) Is the device supplied sterile?		X	If not, please proceed to the next section.
	26) Identify the method of sterilization			Ethylene Oxide - Cycle "J". DHF:Soft PROLENE Mesh

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
	27) Is the sterilization method compatible with the materials?		X	No change to existing Material.
	28) Are the materials stable after sterilization?		X	No change to existing materials.
	29) Is the device design sterilizable?		X	No change to existing materials.
	30) Is the package designed to provide for sterilization of the device?		X	Packaging is Tyvek Copolymer with paper folder.
	31) Has the shelf life of the system been determined?		X	No change to existing materials - DHF: Soft PROLENE Storage Stability
	32) Is the device re-usable?	X		If not, please proceed to the next section.
	33) Are there limitations to the number of re-use cycles?	[redacted]	[redacted]	[redacted]
	34) Are there restrictions to sterilization methods utilized by the user of the device?	[redacted]	[redacted]	[redacted]
8 Sterility - Supplied Non-Sterile	35) Is the device to be disinfected by the user?	X		If not, please proceed to the next section.
	36) Is the method of disinfected and cycle parameters defined?	[redacted]	[redacted]	[redacted]
	37) Is the packaging of the product during sterilization specified?	[redacted]	[redacted]	[redacted]
	38) Does sterilization validation data exist for the recommended sterilization cycle?	[redacted]	[redacted]	[redacted]
	39) Were other methods of sterilization examined?	[redacted]	[redacted]	[redacted]
8 Sterility - Supplied Non-Sterile	40) Has the shelf life of the system been determined?	X		If yes, please specify location of reports.

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
9 Environment	41) .Is the device intended to modify the patient environment?	X		If not, please proceed to the next section.
	42) What is the effect of temperature on the system performance?			
	43) What is the effect of humidity on the system performance?			
	44) What is the effect of atmospheric gas concentration on system performance?			
	45) What is the effect of pressure on system performance?			
10 Measurements	46) Does the device make measurements?	X		If not, please proceed to the next section.
	47) Is there interference of the desired parameter with other possible measurements?			
	48) Is the accuracy of the measurement known at point of use?			
	49) Is the precision of the measurement known?			
11 Interpretive	50) Are conclusions presented by the device based upon measurements, input, or acquired data?	X		If yes, please specify location of software validation reports.
12 Interactions	51) Is the device intended to control or interact with other devices or drugs?	X		If not, please proceed to the next section
	52) If the device is used with other devices or drugs, is there a potential interaction?			
	53) Does the interaction render any safety or functional changes to the device?			
	54) Does the interaction render any safety or functional changes to the other device?			
13 Extraneous Unwanted Energy or Substances	55) Are there any unwanted outputs of energy or substances?	X		If not, please proceed to the next section

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
	56) Does noise affect the device output?			
	57) Does vibration affect the device output?			
	58) Does heat affect the device output?			
	59) Does ionizing radiation affect the device output?			
	60) Does non-ionizing radiation affect the device output?			
	61) Does UV/visible/IR radiation affect the device output?			
	62) Do leakage currents affect the device output?			
	63) Do electric/magnetic fields affect the device output?			
	64) Do contact temperatures affect the device output?			
	65) Does discharge of chemicals affect the device output?			
	66) Does discharge of waste products affect the device output?			
	67) Does discharge of body fluids affect the device's output?			
14 Environmental Influences	68) Is the device susceptible to environmental influences?	X		If not, please proceed to the next section.
	69) Do shipping temperatures affect device safety or functionality?			
	70) Does storage temperatures, humidity, or light affect device safety or functionality?			
	71) Does spillage on the device affect safety or functionality?			
	72) Do fluctuations in the power affect the device output or safety?			
	73) Does variation in the operating temperature, humidity, or light affect the device output or safety?			
	74) Does variation in the operating humidity affect the device output of safety?			
15 Accessories	75) Are there essential consumables or accessories associated with the device?	X		If yes, please state the limits.
16 Preventative Maintenance	76) Is preventative maintenance necessary?	X		If not, please proceed to the next section

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
	77) Can the operator perform preventative maintenance?	[redacted]	[redacted]	[redacted]
	78) Is a specialist needed to perform preventative maintenance?	[redacted]	[redacted]	[redacted]
17 Calibration	79) Is calibration necessary?	X		If not, please proceed to the next section
	80) Can the operator calibrate the device?	[redacted]	[redacted]	[redacted]
	81) Is an external calibration of the device needed?	[redacted]	[redacted]	[redacted]
	82) Is the calibration frequency defined?	[redacted]	[redacted]	[redacted]
18 Software	83) Does the device contain software?	X		If not, please proceed to the next section
	84) Can the operator access the software code?	[redacted]	[redacted]	[redacted]
	85) Are there means to prevent the operator from modifying the code?	[redacted]	[redacted]	[redacted]
19 Shelf-life	86) Does the device have a restricted shelf life?		X	5 years - No change to existing materials - DHF: Storage Stability Committee
	87) Does the package contain an indicator for stability?	X		
20 Long-term Effects	88) Are there any delayed or long-term user effects?	X		
[redacted]	ADD ADDITIONAL CHARACTERISTICS, AS NEEDED	[redacted]	[redacted]	[redacted]

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT

USE RELATED HAZARDS

Place an "X" in the box appropriate for the device being evaluated.	RESPONSE		ACTION
ISSUE	**NO**	**YES**	
1) Have safety or efficacy issues occurred in the use of predicate, or other similar, devices?	X		
2) Could the user incorrectly setup the device that may potentially result in a safety or efficacy event?	X		
3) Identify the critical steps in setting up and operating the device. Can these functions be performed adequately by all of the intended users?		X	See note *
4) Does this device replace an existing device for the same medical procedure or indication for use?		X	If yes, continue to #5; if no, continue to #7
5) Does the device visually resemble the existing device?		X	If yes, continue to #6; if no, continue to #7
6) Will the device operate as intended if it is operated in the manner utilized for the existing device?		X	If yes, continue to #7; if no, explain ramifications.
7) Is the user likely to use the device in a manner other than that described in the Instructions for Use?	X		If yes, explain ramifications
8) Is special training needed for the safe and effective use of the device?	X		If yes, provide plan for accomplishing this training
9) If storage and maintenance requirements are not followed, could use of the device result in an unsafe or ineffective use?	X		If yes, provide plan to mitigate the event.
10) Is safe and effective use of the device complex? Under high stress conditions, could the user become confused such that the device results in an unsafe condition?	X		If yes, provide plan to mitigate the event
11) Are the auditory and visual alarms appropriate for all users and use environments?	X		Device is an implant and does not have alarms.
12) If necessary device accessories are expired, damaged, missing, or different from those recommended, could use of the device result in an unsafe or ineffective treatment?	X		No accessories required for use.
13) Is safe operation of the device resistant to "typical" handling?		X	If no, provide plan to mitigate the event
14) Could device safety be affected if power is lost or disconnected (inadvertently or purposefully); if its battery is damaged, missing or dead?	X		N/A
15) Is the status of the device's connection to the patient apparent where necessary?			Device is an implant and does not connect to the patient for

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Appendix IV

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USE RELATED HAZARDS

Place an "X" in the box appropriate for the device being evaluated.	RESPONSE		ACTION
ISSUE	**NO**	**YES**	
			feedback/monitoring

*The surgeon will apply it in the appropriate area by means of sutures, staples, or other appropriate surgical means.

CONTROL PLAN

LINE NUMBER	HAZARD	SEVERITY of HARM	PROBABILITY of HAZARD	RISK LEVEL	FAULT CLASS	COMMENT	REFERENCES
1	Loss of Mechanical Integrity – Intraoperative	3	2	III	C	Clinical study design will assess this parameter	Ref.: Clinical Literature search
2	Loss of Mechanical Integrity – postoperative	3	1	II	C	Clinical study design will assess this parameter	Ref.: Clinical Literature search
3	Fraying	1	2	I	C		
4	Tear during material handling	1	2	I	C	Clinical study design will assess this parameter	
	Tear during implantation(interference with instrument used during procedure)	1	2	I	C	Clinical study design will assess this parameter	
	Tear after implanted	1	2	I	C	Clinical study design will assess this parameter	
5	Suture Pull out	2	2	II	M	Clinical study design will assess this parameter	
6	Erosion	3	2	III	C	Clinical follow up will assess this parameter	Ref.: Clinical Literature search
7	Sharp edges	1	2	I	S		
11							